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Chemical Right to Know

High Production Volume Chemicals Frequently Asked Questions

What is the High Production Volume (HPV) Challenge Program?

The HPV Challenge Program is a key element of the Chemical Right-to-Know initiative announced this year, on the eve of Earth Day, by Vice President Gore and EPA Administrator Carol Browner. As part of this initiative, EPA, in partnership with industry and environmental groups, created a major ground breaking voluntary chemical testing effort—the HPV Challenge Program. This program was developed to make publicly available a complete set of baseline health and environmental effects data on HPV chemicals. The data are to be collected for each chemical on EPA's list of HPV chemicals (defined as those manufactured in, or imported into, the United States in amounts equal to or exceeding 1 million pounds per year). Testing will be necessary only when existing data are not adequate. The program will generally be carried out in a manner consistent with the internationally-recognized testing protocol (as developed by the Organization for Economic Co-operation and Development (OECD) Screening Information Data Set (SIDS) program) to ensure that the testing can be contributed to the international effort and, conversely, that international SIDS testing and assessments can be used to fulfill the Challenge Program's requirements. The data generated through this program will be made available to the public, fulfilling the EPA's commitment to the public's right-to-know.

What are the benefits of signing up for this voluntary program?

Signing up for the Challenge Program provides an opportunity for recognition as an industry leader on an issue of importance to the public. In the spirit of this right-to-know initiative, the Agency would like to publicly recognize those companies participating in the HPV Challenge Program on its Web Site (*http://www.epa.gov/chemrtk)*. Companies with active product stewardship programs recognize the real importance of filling basic data needs on the chemicals they produce. Much, if not most, of this data can be made available by building voluntary partnerships between EPA and industrial leaders, thus avoiding the necessity for writing rules to obtain test data on HPV chemicals. In addition, the voluntary program allows the use of chemical category approaches which provide some flexibility in the tests to be conducted on each chemical in the category; the test rule will not allow that flexibility. Additionally, the outputs of the voluntary program will be detailed study summaries; the test rule will require submission of entire studies for each of the SIDS test needed for each chemical.

How can a company participate in the HPV Challenge Program?

Participating in the Challenge Program involves sponsoring HPV chemicals from the list published on the EPA's Chemical Right-to-Know web site (*http://www.epa.gov/chemrtk/hpvchmlt.htm*). Sponsors pledge to evaluate the adequacy of existing data and to conduct tests where needed to fill the gaps in the data. A company need not have already performed a detailed review of existing data before making a commitment; this would be provided by sponsoring companies at a later date along with a more detailed testing plan. Companies wishing to participate in the HPV Challenge Program can do so by submitting (on paper, or electronically) a letter of commitment to EPA which identifies the chemicals they will test and a planned start year for the testing. The mailing address for this letter is: Carol Browner, Administrator, US EPA, PO Box 1473, Merrifield, VA 22116, Attn: Chemical Right-to-Know Program. The process for electronic submission of commitments is being finalized, and will soon be made publicly available. Check the Chemical Right-to-Know Web Site (*http://www.epa.gov/chemrtk*) for updates. Suggested sample language for this letter of commitment can also be found at the Chemical Right-to-Know Web Site.

Will EPA publish a list of the companies that participate in the voluntary component of the program?

EPA plans to publish a list of participating companies with their permission.

Which chemicals are on the HPV chemical list?

The HPV chemical list of about 2,800 chemicals was developed from data reported to EPA as required by the Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR) of 1990. EPA has, however, identified some chemicals which are not considered candidates for testing under the HPV Challenge Program based on preliminary EPA review indicating no need for baseline testing. The final list of chemicals can be found on the EPA's Chemical Right-to-Know web site at *http://www.epa.gov/chemrtk/hpvchmlt.htm*.

How often will the HPV chemical list be updated?

The list of chemicals covered by the HPV Challenge Program will not change appreciably once the Program is launched. EPA anticipates that creating baseline health and environmental test data will eventually become routine for newly-identified HPV chemicals, through a combination of domestic and international testing activities. Although newly identified HPV chemicals will not be a part of the HPV Challenge Program, EPA will evaluate the data needs for these chemicals and begin dialogue with domestic manufacturers and OECD SIDS participants to ensure that the information needed for these HPVs is developed in a timely fashion.

What does it mean that the data generated through this program will be available to the public? How will confidential business information be handled?

The principle that the public has a fundamental right to know about the hazards associated with chemicals in commerce is central to this initiative. For this reason, EPA intends to ensure that the information created through the HPV Challenge Program is broadly available to the public, chiefly through the Internet. Therefore, EPA encourages electronic submission of data to facilitate making this

information widely accessible and strongly discourages submission of confidential business information. EPA's Chemical Right-to-Know web site (*http://www.epa.gov/chemrtk*) will house much of the information for the Challenge Program.

What is the relationship between the HPV Challenge Program and any subsequent rulemaking under the TSCA? What will EPA do if chemical manufacturers and importers don't come forward voluntarily to provide data?

EPA plans, if necessary, to make those HPV chemicals not sponsored in the Challenge Program subject to a test rule under Section 4 of the Toxic Substances Control Act (TSCA). Companies that have committed to the program before March 15, 1999 can be assured that sponsored HPV chemicals will not be listed on the proposed test rule. Companies will still have an opportunity to commit to the HPV Challenge Program after the publication of the proposed rule. The program will remain open until December 1, 1999, shortly before the promulgation of the final rule. In addition, although testing chemical categories (instead of each individual chemical) will be encouraged in the Challenge Program, this approach will not be included under the test rule. Inclusion of a chemical in the test rule will also trigger TSCA Section 12(b) export notification requirements.

What do you mean by "chemical categories?"

A chemical category is a group of related chemicals that lend themselves to evaluation and testing as a group. The chemicals can be grouped based on similarities in chemical structure or functionality. If testing is strategically planned, less than the full number of tests for each individual chemical will be necessary and testing costs will be reduced. Examples of categories might include simple (e.g., C_{1-6}) organic acids and their labile salts, fatty alcohols, or aliphatic aldehydes. EPA is working closely with stakeholders to develop a guidance document on categories for use in the Challenge Program. This document will be made available on the EPA's Chemical Right-to-Know web site (*http://www.epa.gov/chemrtk*).

Where can a company find guidance for the tests included in the HPV Challenge Program? Could you define baseline hazard information?

General guidance on participation can be found in the "Principles for Participation in the High Production Volume Challenge Program," available from EPA through its TSCA Hotline at 202-554-1404, or through the web site at *http://www.epa.gov/chemrtk/guidance.htm*. The baseline hazard information has been defined by the Organization for Economic Cooperation and Development (OECD) in its Screening Information Data Set (SIDS). SIDS represents an internationally agreed upon set of tests to screen chemicals and identify potential hazards.

The basic screening endpoints to be tested are: acute toxicity, chronic toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, environmental fate, and physical-chemical properties, and are listed in Section 2.2 (page 2) of "Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals," published in July, 1997. This manual (also called the "SIDS Manual") is available at *http://*

www.epa.gov/sids/sidsman.htm, or obtained as hard copy from OECD Environment Directorate, Environmental Health and Safety Division; 2, rue Andre-Pascal F-75775; Paris Cedex 16, France. Tel: 331-1-4524 9844. Specific information on the SIDS test protocols can be found at: *http://www.oecd.org/ehs/hpv.htm*.

How much will it cost per chemical to complete a full battery of SIDS testing?

EPA projects that the full battery of tests and estimations included in the SIDS testing will cost approximately $250,000 per chemical, assuming that none of the SIDS data are available. Any adequate existing SIDS test data will reduce these costs accordingly. For a further breakdown of costs, please refer to Table 8 in EPA's Chemical Hazard Data Availability Study at *http://www.epa.gov/chemtest/hazchem*.

Can a company share the cost with other manufacturers of the same chemicals?

Yes., EPA encourages companies to work together to avoid duplicative testing efforts. However, when cooperating on testing, companies are advised to bear in mind any restrictions imposed by federal antitrust laws.

Will there be enough laboratory capacity to complete the required testing?

Based on the results of the 1996 "EPA Census of TSCA Testing Laboratories —Final Report" and an assessment of the SIDS testing requirements, EPA believes that there is adequate laboratory capacity to meet most if not all of the demand for testing the HPV chemicals. This report is available through the TSCA Hotline, at 202-554-1404. The timeframe of the Program is adequate for national laboratory capacity to grow to meet any testing demands created by the Challenge Program.

Can companies negotiate the methods for testing with EPA? Will other methodologies besides those found in the SIDS manual meet the EPA's criteria?

The full set of SIDS test data is needed, although exceptions can be made in special circumstances (for example, if chemical instability, reactivity or water solubility prevents carrying out a specific test). In such cases, modifying study procedures or dropping specific tests where circumstances warrant may be appropriate. Testing should be done according to OECD test guidelines *(http://www.oecd.org/ehs/test/testlist.htm*). The SIDS manual can be obtained on the Internet at *http://www.oecd.org/ehs/hpv.htm* or as hard copy from OECD Environment Directorate, Environmental Health and Safety Division; 2, rue Andre-Pascal F-75775; Paris Cedex 16, France. Tel: 331-1-4524 9844.

How will the data from the testing be used? What are the steps for Agency decisions once test data has been submitted?

The intent of EPA's HPV Challenge Program is to gather a basic set of environmental and health effects data for each chemical and make this data publicly available and thereby improve the public's understanding of the toxicity of chemicals most commonly used in this country. The database resulting from this activity will be adequate to support a screening level hazard characterization, which is the first step toward what is known as a risk assessment.

Using this hazard characterization on a given chemical with information about its uses and exposures, EPA and others will then be able to better characterize the potential for adverse human health or environmental effects and decide if further testing or other action is necessary.

Are pesticide inert chemicals included in this HPV Challenge Program?

Yes. If you have conducted testing on your product for EPA's Office of Pesticide Programs, that data may be relevant to the HPV Challenge Program.

Some HPV chemicals were tested years ago. Are these tests still valid?

Tests conducted according to appropriate OECD Test Guidelines (as noted in the SIDS Manual at *http://www.oecd.org/ehs/hpv.htm*) or comparable EPA test guidelines are acceptable. Older studies should be compared to these test guidelines to identify differences in testing procedures and to gauge their possible acceptability. EPA is developing a data adequacy guidance document for this purpose. This document will be made available through the EPA's Chemical Right-to-Know web site (*http://www.epa.gov/chemrtk*). If existing data are determined to be adequate, companies sponsoring a chemical will only need to make these data publicly available by submitting it in summary form to EPA.

How can I find out how much hazard information is currently available on each HPV chemical?

You can find EPA's HPV chemical-hazard information matrix corresponding to the SIDS endpoints at *http://www.epa.gov/chemtest/hazchem.htm#master*. This matrix captures the publicly available information on the HPV chemicals. The Chemical Manufacturers Association published a study entitled "Public Availability of SIDS-Related Testing Data For U.S. High Production Volume Chemicals," June 12, 1998, which may be obtained by contacting the Chemical Manufacturers Association (703-741-5226).

How will the Challenge Program affect small businesses?

EPA is well aware that some of the HPV chemicals are manufactured or imported by small and mid-sized chemical companies. The HPV Challenge Program has been crafted to be flexible and responsive to the concerns of the many different companies and organizations that comprise the chemical industry. Our dialogues with companies and trade organizations have identified particular concerns of small manufacturers, and we have explored adjustments to the Challenge Program to accommodate the needs of small business. We will continue this constructive dialogue as the HPV Challenge Program matures, to ensure that small business concerns are well-represented.

(All documents named above can also be obtained in hard copy via regular mail by calling the TSCA Hotline at 202-554-1404).